How does the law recognize and deal with medical errors?

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DECLARATIONS

Competing interests
None declared

Funding
None

Ethical approval
Not applicable

Guarantor
AFM

Contributorship
AFM is the sole contributor

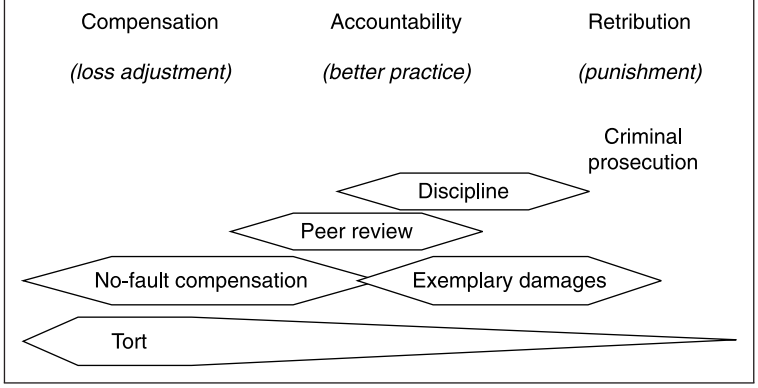
Acknowledgements
This paper is abridged and

Introduction

Two percent of patients admitted to acute care hospitals suffer serious harm from healthcare errors. These errors come to the attention of the law through complaints from patients harmed by them but only a minority of people who suffer harm complain, and most complaints are resolved by local healthcare mechanisms. So the vast majority of medical errors are not dealt with (or even recognized by) the law.

The legal response to medical errors that *do* gain legal consideration is typically dominated by one or more of three goals: compensation, accountability and retribution. These each feature, with greater or lesser emphasis, in different national, legal and regulatory regimes (Figure 1; Table 1). Legislation related to medical registration and professional discipline is often the major mechanism by which the law deals with errors. In practice, policy may be of greater importance than the law itself. In the UK, for example, the likelihood that a fatal hospital error will result in prosecution for manslaughter may have increased in recent years (Figure 2) even though the relevant law has remained unchanged over this period. This probably reflects a change in prosecution policy.[1]

Figure 1
Dealing with accidental harm in health care: the elements of an appropriate response and some mechanisms by which these are usually provided (reproduced with permission from: Runciman B, Merry A, Walton M. *Safety and Ethics in Healthcare: A Guide to Getting it Right*. Aldershot: Ashgate; 2007)



The law, science, moral philosophy and medicine

The law, considered as a system of rules that govern the way people live together, is made effective in part by threat of punishment. From religious or deontological viewpoints, punishment may be seen as justified in its own right; but a consequentialist justification for punishing doctors who, through

Table 1
Some of the organizations and processes through which the law recognizes and deals with medical errors

Internal institutional enquiries and processes (sometimes required by law, e.g. in relation to open disclosure)
Offices safeguarding patients' rights (e.g. that of the Health and Disability Commissioner in New Zealand)
Medical registration bodies (e.g. General Medical Council in England):
• Disciplinary processes
• Competency enquiries
Civil courts:
• Actions for compensatory damages
• Actions for exemplary damages
Coroner's courts:
• Inquests
Criminal courts:
• Prosecutions for manslaughter

adapted from: Merry AF. How does the law recognise and deal with medical errors? In: Hurwitz B, Sheikh A, eds. *Health Care Errors and Patient Safety*. Oxford: Wiley-Blackwell, 2009: 75–88. The author would like to thank Brian Hurwitz for his substantial editorial assistance with this paper

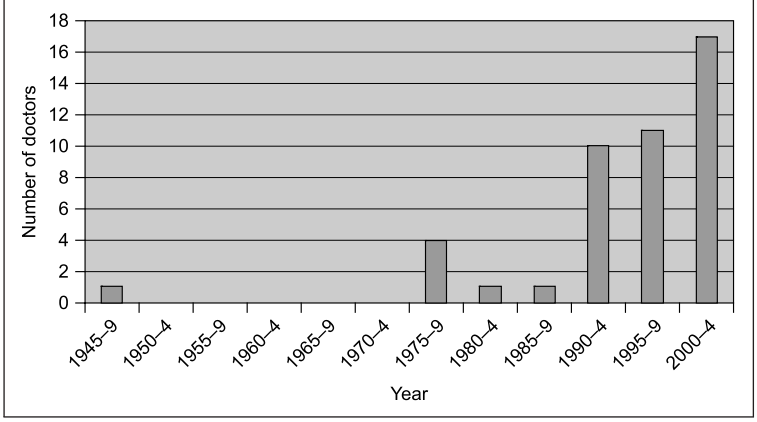
their medical errors, cause harm to patients, holds that this deters other doctors from making the same mistakes in the future. This argument depends on the questionable prior premise that it is actually possible to deter error. Empirical and theoretical considerations suggest that this notion is unsustainable, and that to punish those in error is unjust.

Empirical scientific data on iatrogenic harm and medical error

There are various sources of information on the harm from healthcare (Table 2). The most compelling is a series of studies that screened hospital medical records selected at random for indicators of adverse events; records that screened positive were subjected to detailed, expert review, which showed that adverse events occur in about 10% of admissions to acute care institutions and these contribute to permanent harm or death in about 2% of admissions. After allowing for differences in the precise methods used in each study, the problem appears to be of a similar order of magnitude in the USA, UK, Australia, Denmark, New Zealand and Canada.[2–7]

The most striking examples of preventable and tragic events arising from medical error are provided by the series of disasters involving the anti-cancer agent vincristine, which should be administered only intravenously. It is often given in combination with methotrexate which is administered intrathecally. In Peterborough, in 1990, and at Great Ormond Street Hospital some years later, junior doctors with inadequate specific training and supervision were asked to give these drugs and in the process accidentally confused the routes by which each drug was to be administered. Intrathecal vincristine leads inexorably to a painful death over a period of a week or two, and there does not seem to be any effective treatment. Many of the victims of these mistakes have been children, and it is hard to imagine a more terrible situation for the child, or child's family. It is not surprising that the legal response to errors of this sort has been substantial – in both the Peterborough and the Great Ormond Street cases, the doctors were charged with manslaughter.[8]

Figure 2
Number of doctors prosecuted for manslaughter in the UK in 5-year periods from 1945 to 2004 (data provided by RE Ferner and SE McDowell)



Scientific theory: error, violation and intentional wrongdoing

There is a substantial body of empirical research on the nature of human error, and the cognitive processes by which errors occur.[9,10] A story may best illustrate several key points about human error and about the way it is sometimes dealt with by the law. On 9 June 1995, an Ansett New

Table 2
Sources of information about things that go wrong in healthcare (modified from: Dyer C. Doctor's manslaughter trial halted owing to defendant's death. *BMJ* 2003;327:123)

Medical record review
Routine data collections (deaths, discharges, GP surveys)
Observational studies
Population surveys
Existing registers, reporting systems and audits for:
• morbidity and mortality
• adverse drug reactions
• equipment failure and hazards
Incident monitoring
Complaint investigations:
• hospital and state
• registration boards
• complaints commissioners
Medicolegal investigations
Root cause analyses (sentinel events)
Coronial investigations
Quality improvement and accreditation activities
Results of enquiries and investigations
Literature searches for common and rare events

Zealand Dash 8 aircraft crashed in the foothills of the Tararua Ranges on its approach to Palmerston North Airport on a scheduled flight in bad weather.[11] Owing to a previously unidentified design flaw, there was difficulty in lowering the undercarriage, and the pilot and co-pilot were distracted by undertaking this manually, while continuing to descend flying on instruments in cloud. The Ground Proximity Warning System should have alarmed 17 seconds ahead of impact, but malfunctioned and only provided 4 seconds warning. This was inadequate and in the ensuing collision between the airplane and a hillside, four people died. The police investigated the accident. Three years later they cleared the airline and the co-pilot of any criminal liability[12] but in January 1999, five years after the crash, they charged the pilot with manslaughter.[13] In June 2001, after a jury trial lasting 26 days and involving 22 witnesses and 1000 pages of evidence, he was found not guilty.[14]

This true story illustrates several points:

(1) Errors are unintentional. In simple English, an error occurs 'when someone is trying to do the right thing, but actually does the wrong thing'.[15] In the present example, the pilots were fully engaged trying to sort out a difficulty with their aircraft's undercarriage which, at the time, seemed to be the right thing to do. A more formal definition of error is 'the unintentional use of a wrong plan to achieve an aim, or failure to carry out a planned action as intended';[15]
(2) Errors are not carelessness in the strict sense of the word 'care' – clearly these pilots would have cared a great deal about avoiding a crash;
(3) Pilots sit at the front of the airplane and (unlike doctors) are usually the first to die when things go wrong. It is sometimes alleged that this is one of the reasons for the better safety record of the airline industry than of hospitals. However, the corollary of points 1 and 2 is that deterrence is useless in the prevention of errors. It is noteworthy that the manslaughter charges in relation to the vincristine tragedies in Peterborough and Great Ormond Street have been totally ineffectual in this regard: the same error has now occurred at least 15 times in the UK.[16] It is very unlikely that draconian punishment will reduce the incidence of medical errors;
(4) Experts make errors; all people make errors, but it is often (unrealistically) suggested that experts should get things right, and that errors are unacceptable from trained professionals. The errors made by experts may differ from those made by novices, but they still occur;
(5) The consequences of an error generally depend on more than one factor, and a great deal of luck is involved in this (sometimes referred to as 'moral luck'). Typically, a sequence of events aligns to result in an outcome that might have been averted if any one of the events had not occurred. Underlying defects in the system or environment known as latent factors (in this case the failure in the undercarriage, the failure in the warning equipment and the poor visibility) predispose to error. This principle has been encapsulated by James Reason's 'Swiss cheese' model of accident causation;[17]
(6) The legal response to error significantly depends on outcome. In this case, the key error was that both pilots attended to the undercarriage at the same time; instead, one should have allocated attention to flying the plane while the other dealt with the problem. If the pilots had done exactly the same thing, but circumstances (such as a different geographical setting) had dictated that no adverse event occurred, the error might never have been discovered. If it had been discovered, the response would probably have been minor, and of an internal disciplinary nature. In the airline industry's alleged no-blame culture, the response might even have been constructive and educational rather than punitive. If the same set of circumstances had occurred, but the warning had sounded in time for the pilots to have averted the disaster, the error would no doubt have reached the wider public and the response might have been more severe, but it is unlikely that criminal prosecution would have been involved. Many drug errors are made in healthcare, but only those in which harm results tend to be punished. Punishment is imposed if there are

consequences rather than because of any inherent culpability underlying error;

(7) The legal response to a serious accident is usually prolonged and expensive so it is important that it actually promotes future safety. In a criminal prosecution, the emphasis is placed on establishing the culpability or otherwise of an individual, and enquiry into the underlying causes of an event is often inhibited by the strict rules of process. Tort is certainly a less blame-oriented alternative, but even in civil actions the focus is on establishing the liability of an individual or organization. Moreover, it is quite common for settlements to be made out of court, particularly in the case of egregious violations seen as difficult to defend (see below), when a more investigative legal response might have identified root causes and prevented the occurrence of similar problems in future.

Very similar points can be made concerning medical errors: they are unintended and do not usually represent carelessness, although they may be associated with violations that do represent carelessness, a possibility which requires properly to be discounted. Most practitioners care about their patients and care also about their own professional reputations. Many errors go undetected, but even if detected the initial response, today, tends to be minimal or constructive, provided no one has been harmed. When harm does occur, law suits, discipline or criminal prosecution may well follow. The legal response tends to be proportionate to the *actual* consequences of the error, rather than to potential consequences or the moral culpability involved.

Violation

Many actions that cause patient harm and which are dealt with by the law as 'medical errors' are actually violations. Violations involve choice and are intentional. A simple English definition of violation is: 'an act which knowingly incurs a risk'; 'a deliberate – but not necessarily reprehensible – deviation from safe operating procedures, standards or rules'.[15] Violations may predispose to errors. For example, drinking before driving makes error more likely. When investigating errors, associated violations are relevant to evaluating the degree of moral blame involved. It is not enough to argue that an error was completely unintentional if it was contributed to by an antecedent and morally culpable violation which involved intentional willingness to take risk, albeit no intention to cause harm. It could be argued that a violation was involved in the Dash 8 crash: the correct procedure in circumstances such as these is understood by pilots – one should concentrate on flying the airplane while the other attends to the other problem(s). The key to differentiating violations from errors is the element of intentionality in relation to the breaking of the rule, and this seems to have been absent in this case, but it can be very difficult to establish the mental processes behind a given event or action.

Except in cases of criminal intent violation seldom implies intent to harm: the assumption of the person committing the violation is that he or she will get away with it. Violation usually implies at least some disregard for safety, but not always: occasionally circumstances arise in which violation is unavoidable (in Reason's terms, 'systems double binds'[10]) or when it is appropriate to break a rule, because doing so is thought to create *less* risk than following the rule. In other words, not all violations are equally culpable and each needs to be considered on its merits in the specific circumstances of the case.

Variation in medical practice: a subtle form of medical error

One of the many inconsistencies in the way the law responds to medical error lies in its failure to recognize mistakes which arguably are as culpable and at least as medically significant as events that *do* come to light. John Wennberg demonstrated variation in the provision of certain operations far in excess of that explicable by between patient differences.[18,19] This variability is attributable to differences in approach by doctors and institutions and unsupported by evidence. The implication is that many patients fail to receive operations that are indicated, while others receive operations that they do not need. An unnecessary operation is a form of iatrogenic harm and the decision to undertake it must either be an error or a violation. Unfortunately, the law is very unlikely to elucidate this type of error, even though the potential at this level for improving the overall quality of healthcare is substantial.

Some implications of legal action

In general, law suits, disciplinary actions and internal enquiries are very stressful for the doctors concerned, and so is the publicity that tends to accompany them. To some extent, this is inevitable, but justice arguably requires that such stress should be proportionate to the moral culpability of the actions under review. In this context, there is a substantial difference between most other forms of legal response to medical accidents and a criminal prosecution for manslaughter. This can be appreciated if it is remembered that of the legal processes typically evoked by medical error, only criminal prosecution involves the following:

- Being arrested and taken to a police station for charging;
- Having photographs and fingerprints taken by the police;
- Having to apply for bail;
- Restrictions on international travel;
- Being included on lists for court hearings that include other people charged with crimes like theft, assault and rape;
- The possibility of serving a prison sentence.

All of this may be reasonable in cases of serious moral culpability, such as that of Harold Shipman, but it is much less reasonable in respect of unintentional medical error. The difference was made clear by the judge in one of the vincristine cases, who said: 'You are far from being bad men; you are good men who contrary to your normal behaviour on this one occasion were guilty of momentary recklessness'.[20]

Some basic concepts relevant to the legal response to medical error

The law tends to work through legal rather than scientific concepts.

Duty of care

The legal response to a medical error begins with the question: was there a duty of care? For doctors looking after patients the answer to this question is almost always in the affirmative, but there are circumstances in which some ambiguity may arise. For example, in the vincristine cases one might ask if a senior doctor associated with the case had a duty of care, and if so how well he or she discharged this duty.

Standard of care

The next question is whether the standard of care was adequate. The standard of care required in medical practice is almost always phrased in terms of reasonableness, and failures to meet this standard are generally referred to as negligence or recklessness.

Negligence and recklessness

Negligence is usually defined by some variation on the theme of failing to have and to use reasonable knowledge, skill and care. This is sometimes called 'simple' or 'civil' negligence and is the standard pertaining in the civil courts. Recklessness involves understanding that a risk is incurred in taking (or omitting) an action, but nevertheless choosing to take it: this is the state of mind which characterizes violations. To justify criminal prosecution, most jurisdictions require more than simple negligence, and the term gross negligence is typically used to convey this distinction; in practice the distinction between gross negligence and recklessness may be very subtle.

Reasonableness

Actions in negligence hinge on the question of what is reasonable. A fundamental problem with the concept of 'reasonableness' in this context is that human error is never reasonable. How can it be reasonable, for example, to give a patient the wrong drug? The point generally considered is not whether an action or decision was reasonable, but whether it was one that might have been made by a reasonable person under the circumstances.

Empirical data may be relevant to this question. Data demonstrating that the vast majority of anaesthetists have given the wrong drug at some stage of their career[21] show that giving the wrong drug may be the sort of error any reasonable anaesthetist could make on occasion. On the other hand, if an anaesthetist had chosen not to put labels on his or her syringes when preparing several for use in a case, this violation of a widely understood and accepted rule antecedent to the error in question,

might be construed as something a reasonable anaesthetist would never do.

How the law works in practice

In most parts of the world, a primary objective of litigation is compensation. But in order to obtain compensation, the patient must prove negligence and also that the particular negligence concerned caused the harm that is to be compensated. Causation may be more difficult to prove than breach of duty because of uncertainties inherent in medical practice, and the difficulty in proving causation in the case of particular individuals in a way that goes beyond more than 50% probability. Whatever the outcome in respect of compensation, the process also punishes the doctor by its impact on his or her reputation, through the stresses involved in the legal process and through the inevitable publicity associated with it. Sadly, patients often feel that they too have been punished, because the proceedings tend to be unpleasant and impersonal for all concerned. The vast majority of cases in some jurisdictions are settled out of court, and this tends to maximize the emphasis put on compensation and reduce that put on punishment. Ironically, the more egregious the case, the more likely it is to be settled in this way. Occasionally, courts impose exemplary damages with the express purpose of punishing a doctor or institution.

Overall, litigation seems an inefficient and unreliable way of providing compensation for harm arising from medical error. It is often said that it is better than the alternatives, but the no-fault systems of compensation in New Zealand and Scandinavia seems to work to the satisfaction of these countries' populations. On the other hand, the threat of litigation may be of some value in increasing investment in safety. Conversely, it might produce perverse effects, such as increased insurance premiums for certain groups of doctors, which tend to be passed on to consumers in the form of an increase in the cost of healthcare.

Should medical error be tolerated?

The fact that medical error often involves little or no moral culpability is an argument against a punitive legal response to it, but it is not an argument for tolerating medical errors or suggesting errors do not matter. If it is accepted that many errors occur and produce harm largely through predisposing factors in healthcare systems, then it seems obvious that punishing the doctors who make them without addressing these factors is unlikely to prevent a recurrence of the errors (and this has certainly been true in the case of the vincristine disasters). The fact that terrible harm has occurred to a patient may not, in itself, be a reason to punish someone, but it is, absolutely, a reason to take all reasonable steps to prevent such errors happening again. It is perverse in the extreme that few limits seem to be placed on the resources expended in the legal response to medical accidents once the courts are involved, but strict limits are applied to proactive investment into safety in healthcare. It is therefore critically important that the legal response to accidents in healthcare should promote safer practice.

The ideal legal response to medical errors that result in harm to patients

When a patient is harmed by a medical error the highest priority is timely and free provision of the healthcare needed to minimize that harm. An acknowledgement of the fact that something has gone wrong, an empathic apology and an explanation are all essential, and should be given early and readily. This requirement has been called 'open disclosure' and is becoming enshrined in the policies of institutions and legislation of many countries.

Appropriate compensation should be provided as of right, and should include the costs of any healthcare and rehabilitation and any loss of earning capacity arising from the accident. Ideally, compensation should not be linked to the need to prove fault (as it is in litigation). An appropriate analysis of why things went wrong and a concerted effort to correct any failings in the system and minimize the likelihood of a recurrence is essential. The concept of a 'no-blame culture' is hard to sustain. Rather, the aim should be for a 'just culture' in which blame is restricted to those circumstances in which it is morally appropriate. In dealing with medical errors for which, by definition, moral culpability is low the primary objective of both the legal and the medical systems should

be the promotion of safe and effective healthcare.[10] The focus should therefore be on those who do have the influence or authority to make changes which promote safety within the healthcare system. Prosecuting or suing practitioners who have no such influence or authority, such as junior doctors, simply sets the scene for the same errors to be made again.

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